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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,778	09/22/2000	Thomas Specht	SCH-1768	7796

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EXAMINER
LIU, SAMUEL W

ART UNIT	PAPER NUMBER
1653	9

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,778	SPECHT ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41* is/are pending in the application.

4a) Of the above claim(s) *1-24,26,28 and 36-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,25,27 and 35* is/are rejected.

7)☒ Claim(s) *35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Preliminary amendment (filed 22 September 2000) of claims 5-12, 14-15, 17, 19-20, 31-4, 36-38 and 41 have been entered. Also, applicant's response filed 5 August 2002 as to request for extension of time of one-month has been entered.

Foreign priority

Applicants' claim for foreign priority under 35 U.S.C. 119 (a)-(d) is acknowledged. The copy of the German 198 17 557.4 has been received.

Restriction/Election

Applicant's election without traverse of Group V, claims 24-27 and SEQ ID NO:288 (Paper No. 8) filed on August 5, 2001 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Note that claim 26 is withdrawn from further consideration as being dependent on non-elected claim 22. Therefore, the pending claims 24-25, 27 and 35 with SEQ ID NO:288 are examined in this Office action.

Specification/Claim/ Objections

The disclosure is objected to because of the following informalities:

(1) In page 3, line 7, 'Seq ID Nos." should be changed to "SEQ ID NOs:"; the same change should be made throughout the specification.

(2) In page 5, line 2, "pBs KS" should be changed to "pBSKS".

(3) In page 8, line 9, "BAC" and PAC" should be spelled out for the first instance of use.

(4) In claim 35, the article "A" is missing before the recitation "pharmaceutical agent".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 24-25 and 27 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 24-25 and 27, as written, do not sufficiently distinguish over polypeptide, proteins, cells and antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980).

Claims 24-25 and 35 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a well-established or disclosed specific and substantial credible utility.

The claimed polypetide is not supported by a *specific asserted utility* because the disclosed polypeptide is not actually isolated or purified and characterize, but rather predicted from polynucleotide that is product of analyzing database (*e.g.*, LifeSeq database – EST libraries), and because use of the claimed polypeptide relies on electronic Northern Blot, i.e., a contemplative analysis of the data from the databases.

The specification sets forth use of the claimed polypeptide subsequence (*i.e.*, the partial sequence), the fragment possessing 80% sequence identity to SEQ ID NO:288, to identify composition against cancer, *i.e.*, treating cancer disorder state (see page 7, the fourth paragraph). However, there is no working examples nor guidance as to how to make and use it in the specification regarding the claimed subsequence; the specification only provides evidence for algorithm of identifying cDNA encoding the polypeptide SEQ ID NO:288 with altered expression using tissue-specific electronic Northern Bolt (see Example 2). Note that electronic Northern blot does not represent reasonable establishment in reducing the invention to practice, but rather a contemplation of the claimed composition. Thus, there is no specific utility and substantially utility associated with the claimed protein.

Also, the specification as filed does not provide experimental evidence that points to an activity (biological role or/and therapeutic role) of the polypeptide SEQ ID NO:288. Additionally, there is no art of record that discloses or suggests any activity for the claimed polypeptide. Thereof, there is no substantial utility associated with the polypeptide.

The specification sets forth that the invention relates to pharmaceutical agent containing the claimed polypeptide (see page 7, the last two lines). Yet, nowhere in the specification describes factual evidence in this regard, e.g., provides animal model or experimental data to support what is claimed.

The specification sets forth that the claimed polypeptide can be use as pharmaceutical agent for treating ovarian cancer (see page 7, the paragraphs 4-6, and claim 35). The specification appears to correlate candidate genes that is EST-database orientated as well as tumor-related (see Example 1) with the claimed composition based on the altered mRNA

expression pattern of the genes (see Example 2). Such the apparent correlation does not have intrinsic input on the specific utility of the current disclosure because, at present, it has been widely accepted that the actual steady state level of mRNA molecules, is not well correlated with the actual protein abundance (see Aebersold, R. et al. (2000) *Annals of the New York Academy of Sciences* 919, 33-47), and because numerous proteins undergo *up* or *down* cellular regulation responsive to the extracellular signals and intracellular signaling (*i.e.*, cell signaling pathways cross-talk). Since the examples set forth in the specification does not suffice establishing the anti-cancer function of the claimed polypeptide, and since the current application only provides working example and guidance as to the altered gene expression that relies on algorithm, *e.g.*, electronic Northern Blotting analysis, which is not necessarily and sufficiently for supporting that the expressed protein level is proportional to the expressed polynucleotide level thereof, there is no specific and sensational utility or well-established utility associated with the claimed polypeptide.

Applicant is not in possession of the claimed polypeptide and subsequence that is 80% identical to SREQ ID NO:288 and pharmaceutical agent comprising the polypeptide or/and subsequence thereof.

Subsequences, as noted *supra*, the instant claim language appears to encompass subsequences. For example, claim 24 recites polypeptide partial sequences of SEQ ID NO:288 polypeptide, and claim 25 recites polypeptide of at least 80% homology to the partial sequence. Such the recitations do not require that the full-length sequence set forth in SEQ ID NO:288; but rather encompasses any amino acid sequence comprising either the SEQ ID NO:288 or *any subsequence*. Neither does the specification appear to have provided any working examples of

any functional subsequences. Thus, it would require undue experimentation for the skilled artisan to determine which subsequences of SEQ ID NO:288 would have the function of the full length molecule, provided that the full length molecule has a biological activity.

One of skill in the art would reasonably conclude that the disclosure insufficiently provides written description regarding the biological activity or role(s) of the claimed polypeptide and fragments (*i.e.*, subsequences). The specification provides insufficient teaching, guidance and no working examples as to make and use of the protein in treating cancer. Thus, Applicant was not in possession of the pharmaceutical composition comprising the claimed polypetide and the fragments (subsequences of the polypetide) therteof. *See University of California v. Eli Lilly and co. 43 USPQ2d 1398.*

In addition, the specification sets forth that a protein (*e.g.*, antibody) that binds the polypeptide or subsequence thereof (see claim 35). There are no examples and guidance, however, provided in regard to this. The skilled artisan would not know to how to make and use the polypeptide or subsequence thereof. Until some actual and specific significance can be attributed to the protein identified in the specification as the protein SEQ ID NO:288 or/and the subsequences thereof, one of ordinary skill in the art would have been required to performed undue experimentation in order to determine how to practice the claimed invention. Thus, the claims are not fully enable for all the polypeptide subsequences and the molecules binding to the subsequences as presently claimed.

Description of invention's reduction to practice, unaccompanied by any meaningful, distinguishing characteristics of evolved the polypeptide variants, *i.e.*, subsequence fragments, is insufficient to satisfy written description requirement of 35 U.S.C. §112, since inventors could

have provided description of claimed portion of SEQ ID NO:288, since actual reduction to practice may demonstrate possession of embodiment of invention, but it does not necessarily describe what invention is, and since, in context of present case, disclosure of manner in which invention was reduced to practice does not satisfy more fundamental written description requirement set forth in Section 112.

After further search, a specific and substantial credible utility might be found for the claimed isolated compositions. This further characterization, however, is part of the act of the invention and until it has been undertaken, applicants' claimed invention is incomplete. The current disclosure is therefore deemed lack of specific and substantial utility or well-established utility.

Claims 24-25 and 35 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation. This rejection stands for the reasons set forth in the foregoing statement of the grounds of rejection under 35 U.S.C. 101.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24 and 35 recite the non-elected sequences of SEQ ID NOs: 124-257, 274-287 and 189-307 which are patentably distinct from the elected sequence SEQ ID NO: 288 and drawn to non-elected invention. Such the recitation renders the claims indefinite. Thus, re-writing the claim is advised in order to eliminate the subject matters which have been withdrawn from consideration in this Office Action.

Claim 25 recite "at least 80% homology" is unclear because the recitation encompasses undisclosed upper limit of the percentage of homology. In addition, claim 25 is vague as to "these sequences"; to which sequence does the claim recitation refer?

Claim 27 recites "phage display"; the recitation is unclear regarding whether or not the recitation refers to a phage display technology, or phage display protein libraries, or antibody phage display libraries. Also, clam 27 recites "developed"; the recitation is not apparent as to whether or not the claimed polypeptide is actually obtained from a phage display technology. Further, claim 27 is unclear as to "that can bind to …", wherein "can" renders the claim indefinite, since it does not equate to indication the specific binding must actually occur.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 25 is rejected under 35 U.S.C. 102 (a) as being anticipated by Kato, S. *et al.* (WO 9811217, issued on March 19, 1998).

Kato *et al.* disclose a polypeptide sequence that is ~84% identical (see page 79, SEQ ID NO:10) to the peptide sequence SEQ ID NO:288 of the current application.

Provisional Rejection - Obviousness Type Double Patenting

Claims 24-24 and 35 of this application conflict with Claims 23, 26 and 32 of Application No. 09674266. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22, 25 and 35 are provisionally rejected under the judicially created doctrine of double patenting over claims 23, 26 and 32 of copending Application No. 09674266. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claim 23 of Application 09674266 claims the polypetide (SEQ ID NO:181) that is identical to the polypeptide (SEQ ID NO:288) disclosed in the instant application.

Claims 26 of Application 09674266 and claim 25 of the current application set forth the polypeptide is at least 90% and 80% homologous to the SEQ ID NO:181 and SEQ ID NO:181, respectively. Although the claims are not identical, they read on each other; thus, they are obvious variation from each other.

Claim 32 of Application 09674266 and claim 35 of the current application disclose the common subject matter, *i.e.*, a pharmaceutical composition comprising the claimed polypeptide.

Therefore, the instant application and Application 09674266 claims are obvious variation, and they are not patentably distinct from each other.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

Samuel Wei Liu, Ph.D.

February 27, 2003